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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,973	08/02/2006	Jairam R Lingappa	UCSF.011.00US	7515

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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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06/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,973	Applicant(s) LINGAPPA ET AL.	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply with Sequence Rules</u> . |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/26/2005, 7/18/2005 & 8/24/2006.

DETAILED ACTION

Applicants' election with traverse of Group X in the reply filed on February 15, 2008 is acknowledged. The traversal is on the grounds that there is no search burden. This is not found persuasive.

Search burden is not a factor for determining how claims are restricted in applications filed under 35 U.S.C. §371. According to the M.P.E.P., restriction practice under M.P.E.P. § 806 is applied to national applications filed under 35 U.S.C. § 111(a) while unity of invention practice under MPEP Chapter 1800 is applied to national stage applications (see M.P.E.P. § 201).

According to PCT Rule 13.2 (Unity of Invention), where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

As stated in the Restriction Requirement dated September 11, 2007, Groups I, II, VII, VIII, IX and X do not have a technical feature in common, and thus, lack unity with each other. The technical feature shared among the inventions listed as Groups III and IV is a compound that inhibits capsid assembly, and the technical feature shared among the inventions listed as Groups V and VI is a capsid intermediate comprising a host protein. The noted shared technical features do not provide a contribution over the prior

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art, as evidenced by the teachings of Sakalian et al. (JOURNAL OF VIROLOGY, June 1996, 70(6):3706–3715). Sakalian et al. discloses a system to determine if a viral protein (e.g., gag mutant) is required for capsid assembly (see Abstract and pages 3709-3710). The system demonstrates that, for example, a mutant gag protein fails to assemble in vitro. Sakalian et al. further discloses use of the cell-free system to identify potential inhibitors (e.g., anti-Gag antibodies) of virus assembly, and Sakalian et al. isolated intermediate assembly complexes with chaperonin (see page 3713). Hence, in the absence of a contribution over the prior art, the noted shared technical feature is not a shared special technical feature. Without a shared special technical feature, the inventions listed as Groups II and IV and Groups V and VI lack unity with one another.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: Pages 38 and 49 contain nucleotide and amino acid sequences, however, there is no sequence listing in paper or computer readable form. See the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Appropriate correction is required.

The amendment filed on January 30, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added

material which is not supported by the original disclosure is as follows: Applicants updated the first line of the specification (continuity data) via a Preliminary Amendment filed on January 25, 2007. This amendment stated "This application is a 371 of PCT/US2004/028622, filed September 11, 2003, which claims benefit of U.S. Provisional Application Serial No. 60/410,572, filed September 13, 2002." However the Preliminary filed on January 30, 2008, to correct the PCT application number states "This application is a 371 of PCT/US2003/028622 filed, September 11, 2003, which claims benefit of U.S. Provisional Application Serial No. 60/410,572, filed September 13, 2002, both of which are incorporated herein by reference in their entirety for all purposes." The phrase "both of which are incorporated herein by reference in their entirety for all purposes" is new matter as it was not part of the originally filed disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

The drawings are objected to because Figures 18, 20 and 25 have the word "Figure" partially cut off. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

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and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The antibodies of claim 25 read on natural antibodies to the virus. Even though the virus is non-naturally occurring, it does not mean that a natural antibody would not bind to the capsid proteins. It is possible that the non-natural aspect of the virus occurs in a non-capsid protein (e.g., envelope or another structural protein) that would not affect the naturally-occurring antibody binding to the viral capsid protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al. (Journal of General Virology, 1994, 75:895-900).

The claims are directed to antibodies to viral capsids of a non-naturally occurring virus.

McGuire et al. discloses infected cells with recombinant vaccinia viruses expressing the equine infectious anaemia virus (EIAV) gag gene (VGag) or gag plus the 5' pol encoding protease (VGag/PR). The cells were evaluated with monoclonal antibody to a p26 capsid protein linear epitope (QEISKFLTD) (see, for example, the abstract and page 896, left column).

The recombinant vaccinia virus of McGuire et al. is non-naturally occurring and the monoclonal antibody is directed to the p26 capsid protein.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (Virology, 1996, 217:252-261).

The claims are directed to antibodies to viral capsids of a non-naturally occurring virus.

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Hardy et al. discloses infecting insect cells with recombinant baculovirus expressing Norwalk virus (NV) capsid protein. Hardy et al. also discloses monoclonal antibodies that recognize the rNV capsid proteins expressed in the infected insect cells (see, for example, the abstract and page 252, right column).

The recombinant baculovirus of Hardy et al. is non-naturally occurring and the monoclonal antibody is directed to the capsid protein of the recombinant virus.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648